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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RUTH LARA, individually and as guardian of her minor child J.S., on behalf of themselves and those similarly situated, Plaintiffs, v. PUFF BAR, NICK MINAS, PATRICK BELTRAN, COOL CLOUDS DISTRIBUTION, INC., UMAIS ABUBAKER and SHAHID SHAIKH, Defendants.	Case No. 2:20-cv-08030-SDW-LDW

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION TO DISMISS SECOND AMENDED COMPLAINT

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Plaintiffs' opposition does not address the Amended Complaint's pleading deficiencies that Puff Bar raises in its motion to dismiss. Plaintiffs mischaracterize the tenets of express preemption which bar their New Jersey Product Liability Act ("PLA") claims and fail altogether to address Puff Bar's arguments regarding implied preemption. Even if their failure to warn claim under the PLA was not preempted, Plaintiffs fail to allege any facts rebutting the PLA's presumption that Puff Bar's FDA-mandated warning is legally sufficient. Similarly, as regards their design defect claim under the PLA, Plaintiffs fail to account for the clear notice on Puff Bar's product labeling that the products contain up to five percent "nic salts" that are addictive and also fail to identify a technologically feasible and practical alternative design that would reduce or prevent the alleged harm of nicotine addiction without substantially impairing the intended function of Puff Bar's products. Plaintiffs' Second Amended Complaint should be dismissed with prejudice.

REPLY TO PLAINTIFFS' FACTUAL ALLEGATIONS

Plaintiffs' Opposition contains numerous "allegations" regarding Puff Bar's alleged marketing and sales activities and youth that either are not found at all in the Amended Complaint or, if pled, are only presented in a summary fashion and lack appropriate factual support. By way of example, claims that Puff Bar's products are "made accessible to youth," Am. Compl., ¶ 146, are nothing more than a "naked assertion devoid of further factual enhancement" that need not be granted any deference by the Court, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). Moreover, Plaintiffs may not supplement their complaint through their briefing on a motion to dismiss. *Janowski v. City of N. Wildwood*, 259 F. Supp. 3d 113, 130 (D.N.J. 2017).

In reality, the unfounded allegation that Puff Bar markets its product to minors is nothing more than an attempt to deflect attention away from the uncontroverted fact that minor Plaintiff J.S. illegally purchased the Puff Bar product he claims harmed him. As pointed out in Puff Bar's opening memorandum, Plaintiffs do not allege that any Puff Bar products were purchased directly

from Puff Bar. It is remains unpled and unknown how Plaintiff J.S. purchased the Puff Bar products and from which New Jersey retailer(s) he purchased them, as the retailer(s) is/are not named in this lawsuit. Also unknown is whether Plaintiff J.S. misrepresented his age or presented fraudulent identification documents to the unidentified retailer(s) to do so. Nor do Plaintiffs allege whether Plaintiff J.S. purchased the Puff Bar product(s) once or several times, whether he purchased one or multiple products at a time, or whether he purchased any Puff Bar products other than the Puff Plus. *See* Compl., ¶8. Significantly, there are no allegations even specifying the stated nicotine content of the Puff Bar product(s) allegedly purchased and consumed by J.S. Nowhere do Plaintiffs address these deficiencies, including by suggesting plausible inferences.

Despite the fact that they are clearly found on the face of the Amended Complaint, also notably absent from Plaintiffs' recitation of the relevant facts is any reference to either the FDA-mandated nicotine addictiveness warning or to the words "5% SALT NIC" on the Puff Bar products' labels. Am. Compl., ¶ 69.[1] As discussed below, these features of Puff Bar's product labeling require dismissal of Plaintiffs' claims with prejudice.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE EXPRESSLY AND IMPLIEDLY PREEMPTED BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT

As noted in Puff Bar's opening memorandum, Plaintiffs' claims under the New Jersey PLA are both expressly and implied preempted by the FDCA. Section 916 of the FDCA expressly preempts Plaintiffs' design defect claims regarding the nicotine content of Puff Bar's products because Plaintiffs' claims seek to impose different or additional "tobacco product standards" than

[1] The product images found at paragraph 69 of the Amended Complaint illustrate the "5% SALT NIC" language on the front label of the Puff Plus product that was allegedly used by minor Plaintiff J.S. Am. Compl., ¶ 8. For the Puff Bar product, the words "Salt Nicotine: 5%" are found on the back label of the package.

those imposed by FDA. Section 916 also expressly preempts Plaintiffs' failure-to-warn claims regarding the products' labeling and nicotine warning because such claims seek to impose different or additional labeling requirements than those imposed by FDA. Plaintiffs' claims are also impliedly preempted because the Amended Complaint seeks injunctive relief that amounts to an effort to privately enforce the FDCA. Finally, to the extent Plaintiffs seek to premise their PLA claims on allegations of false advertising, the Amended Complaint contains insufficient factual allegations to provide a basis for doing so.

A. Plaintiffs' Design Defect Claims Regarding Puff Bar's Products are Expressly Preempted.

Plaintiffs' design defect claims under the PLA are expressly preempted by Section 916 of the FDCA. While Plaintiffs' Amended Complaint is replete with factual allegations unrelated to Puff Bar or its products, Puff Bar understands the crux of Plaintiffs' design defect claim under the PLA to be that Puff Bar's products are defectively designed because (i) they contain nicotine salts, which lessen the "throat hit" for non-smokers and facilitate nicotine absorption, thereby increasing the products' addictiveness and attractiveness to youth; and (ii) the nicotine content of the products is up to five percent, which also increases the products' addictiveness. Both of these prongs of Plaintiffs' design defect claim are barred by Section 916(a)(2)(A) of the FDCA.

Section 916(a)(2)(A) bars state requirements that are "different from, or in addition to," requirements under the FDCA relating to, *inter alia*, "tobacco product standards." 21 U.S.C. § 387p(a)(2)(A). As noted in Puff Bar's opening memorandum (page 12), tobacco product standards include provisions governing "nicotine yields," "measurement of . . . tobacco product characteristics," and "construction, components, ingredients, additives, constituents . . . , and properties of the tobacco product." 21 U.S.C. § 387g(a)(4). Because Plaintiffs' PLA claims would have the Court hold that a tobacco product containing a nicotine salt formulation or a nicotine

content of five percent or more was defectively designed under New Jersey law, Plaintiffs would have the court force Puff Bar to "alter 'the construction, components, ingredients, additives, constituents . . . and properties' of [the Puff Bar] products," thereby "infring[ing] on the FDA's authority to determine what chemicals and processes may be used in making tobacco products.'" *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 434 (2d Cir. 2013).

In their Opposition, Plaintiffs cite to general principles governing preemption that largely apply to circumstances where no express preemption clause exists. Because Congress saw fit to include Section 916 in the Tobacco Control Act, those principles are largely inapposite here. After a lengthy "wind-up" of similarly irrelevant references to legislative history, Plaintiff's Opposition fails to meaningfully respond to Puff Bar's contention that Plaintiffs' claims about the Puff Bar products' nicotine content, flavors, and other characteristics take direct aim at the products' construction, components, ingredients, and nicotine yields and seek to establish additional "tobacco product standards" for them under New Jersey law. Because Section 916 of the FDCA reserves the power to set and address these standards to FDA, Plaintiffs' claims are expressly preempted.

Nor is it the case, as Plaintiffs contend, that Section 916(b)'s statement that the FDCA's provisions regarding tobacco products are not intended to "modify or otherwise affect any action or the liability of any person under the product liability law of any State" somehow saves Plaintiffs' preempted design defect claims. 21 U.S.C. § 387p(b). Plaintiffs' reading of Section 916(b)—that any claims relating to design defects or alleged failures to warn relating to a tobacco product are not preempted merely because they are encompassed by New Jersey's Product Liability Act—would largely eviscerate Section 916(a)(2)(A) of any meaning whatsoever. Indeed, it would allow plaintiffs and courts in different states to set different *de facto* standards regarding the ingredients,

properties, and construction of, and warnings required for, tobacco products under the guise of state product liability law. That is not what was Congress intended in enacting Section 916(b).

B. Plaintiffs' Failure to Warn Claims Regarding Puff Bar's Products are Expressly Preempted.

Plaintiffs' failure to warn claims are similarly expressly preempted by Section 916(a)(2)(A). Part B of Plaintiffs' First Cause of Action alleges that Puff Bar failed to warn that its products expose the consumer to nicotine, may cause nicotine addiction, "[t]hat Puff Bar delivered more nicotine than cigarettes," and that Puff Bar failed to "adequately warn about the risk of nicotine addiction" and other alleged risks of use. Am. Compl., ¶¶ 147, 150. As explained in Puff Bar's opening memorandum, these state-law claims are expressly preempted under Section 916(a)(2)(A) because they would impose additional or different requirements relating to "labeling," 21 U.S.C. § 387p(a)(2)(A), than those found in 21 U.S.C. §§ 387c(a)(2), 387t(a)(1), and 21 C.F.R. § 1143.3(a)(1)-(2). Of greatest moment here, 21 C.F.R. § 1143.3(a)(1)-(2) contains specific location, color, font, and size requirements for a nicotine addictiveness warning that is actually found on all of Puff Bar's products: **"WARNING: This product contains nicotine. Nicotine is an addictive chemical."** These labeling mandates preempt Plaintiffs' failure to warn claim. *See In re Fontem US, Inc.*, No. SACV 15-01026 JVS (RAOx), 2016 U.S. Dist. Lexis 187853, at *7 (C.D. Cal. Nov. 1 2016) ("The preemption analysis is straightforward: the FDA, under the authority it possesses under the TCA, *see* 21 U.S.C. § 387f(d)(2), has promulgated a labelling requirement that applies to e-cigarettes. Therefore, state labeling requirement that apply to e-cigarettes that are different from, or in addition to the FDA's requirement are preempted.").

Despite FDA's clear and detailed regulation of e-cigarette warnings, Plaintiffs nonetheless make a claim for failure to warn, alleging that Puff Bar failed to warn about the risk of nicotine addiction, about the amount of nicotine being delivered in its products, and about the consequences

of nicotine addiction. Plaintiffs' proposed warning requirements both intentionally ignore the clear language of the existing warning on Puff Bar's packaging ("WARNING: This product contains nicotine. Nicotine is an addictive chemical."), and seek to impose additional, different requirements. As the *Colgate I* court noted, "[i]f Plaintiffs' claims [seeking to require Juul to include warnings regarding greater potency of its formulations] were allowed to go forward . . . , it would constitute a usurpation of the power vested in the FDA by Congress to regulate the content of the warnings on covered tobacco products." *Colgate v. Juul Labs, Inc.*, 345 F. Supp. 3d 1178, 1188-89 (N.D. Cal. 2018) ("*Colgate I*").[2] The same is true here, and Plaintiffs' claims are preempted and must be dismissed with prejudice.

In their Opposition, Plaintiffs essentially advance two arguments: (1) because Puff Bar has not yet received a marketing order from FDA for its products under Section 910 of the FDCA, it cannot invoke Section 916's express preemption language; and (2) Plaintiffs' claims only "parallel" federal labeling requirements, and thus are not preempted. Both these contentions fail.

First, contrary to Plaintiffs' contentions, the FDCA contains no requirement that a manufacturer or distributor of a tobacco product secure a marketing order from FDA prior to enjoying protection from state law claims subject to the express preemption language of Section 916 of the FDCA. Indeed, to date, no ENDS product has received a marketing order authorization from FDA.[3] Nevertheless, federal courts have repeatedly found state law claims to be preempted

[2] The *Colgate I* court did permit a failure to warn claim to proceed against Juul. However, that claim was permitted to proceed as a result of an allegation that Juul's label expressly represented nicotine levels to be 5% when the actual percentage was 6.2%. 345 F. Supp. 3d at 1189. There is no allegation of such an express misrepresentation on the label here.

[3] *See* FDA Center for Tobacco Products, Premarket Tobacco Product Marketing Orders, *available at* https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders (listing only marketing orders for Swedish Match snus, Philip Morris's heat-not-burn IQOS system and heatsticks, and 22nd Century Group, Inc.'s reduced-nicotine combustible cigarettes).

by Section 916(a)(1)(A)'s limits on state law requirements relating to tobacco product labeling. *See, e.g.*, *Colgate I*, 345 F. Supp. 3d at 1187-89 (holding preempted claims that Juul's labeling failed to adequately warn of risks of nicotine addiction resulting from nicotine salt e-liquid formulation, including specifically claims arising prior to FDA's assertion of jurisdiction over ENDS products through Deeming Rule on August 8, 2016); *In re Fontem US Consumer Class Action*, No. 15-cv-01026, 2016 U.S. Dist. LEXIS 187853 (C.D. Cal. Nov. 1, 2016) (holding preempted state law claims related to alleged failures to warn on labeling of certain risks of nicotine and other ingredients), and 2017 U.S. Dist. LEXIS 230139, at **7-14 (C.D. Cal. Mar. 8, 2017) (applying earlier holding to claims that arose prior to FDA's assertion of jurisdiction over ENDS products through Deeming Rule on August 8, 2016); *see also Yimam v. Mylé Vape, Inc.*, No. 2019 CA 008050 B, 2020 D.C. Super. LEXIS 7, at **11-12 (D.C. Super. Ct. June 11, 2020) (holding expressly preempted claim that ENDS manufacturer was required under District of Columbia Consumer Protection Procedures Act to affirmatively disclose lack of FDA marketing order on its product labeling).[4]

Second, Plaintiffs' failure to warn claims do not merely "parallel" FDA requirements, as Plaintiffs contend, but rather are "different from" and "in addition to" the FDA-mandated labeling requirements found in 21 U.S.C. §§ 387c(a)(2), 387t(a)(1), and 21 C.F.R. § 1143.3(a)(1)-(2). While Plaintiffs' Amended Complaint fails to specify exactly what Plaintiffs believe an adequate warning of the product's risks would look like, the Amended Complaint appears to allege that a

[4] Indeed, the cases cited by Plaintiffs interpreting the Medical Device Amendments' ("MDA") preemption clause are wholly inapposite, as they deal with a different statutory scheme containing entirely distinct operative language. *See* 21 U.S.C. § 360k(a) (providing that no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement which, *inter alia*, "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter").

greater warning regarding the risks of nicotine addiction should be required, as the FDA-mandated nicotine warning present on the products "fails to adequately warn about the risk of nicotine addiction." Am. Compl., ¶ 147. The Amended Complaint also appears to allege that additional warnings should be required, including warnings that the product's nicotine content is "as much as two to three times as high as that in a pack of cigarettes"; that the product "cause[s], maintain[s], or aggravate[s] nicotine addiction and subject[s] consumers to the risks of concomitant health hazards"; that the product "deliver[s] more nicotine than cigarettes"; and that the product's "pharmacokinetic profile ha[s] been engineered to create risks of abuse and addiction that exceed] th[ose] of a cigarette." *Id.*, ¶¶ 147, 150. None of these allegedly "omitted" warnings is required by the comprehensive labeling requirements found in the FDCA and FDA's regulations applicable to ENDS products. The warnings that Plaintiffs claim are lacking from Puff Bar's products are necessarily, then, "different from" and "in addition to" those mandated by the FDCA. Plaintiffs' failure to warn claim is thus preempted in its entirety.[5]

C. The Amended Complaint Lacks Sufficient Factual Allegations to Support a PLA Claim Premised on False Advertising.

Perhaps recognizing the legal inadequacy of their claims premised on alleged design defect and failure to warn, Plaintiffs also attempt to shoehorn their PLA claims into Section 916(a)(2)(B)'s exception for state laws prohibiting false advertising. Even if their claims could fit

[5] Additionally, because Plaintiffs have failed to respond in any discernable manner to Puff Bar's contentions that the Amended Complaint's claims are also impliedly preempted because they attempt to privately enforce the FDCA's requirements and seek, *inter alia*, an injunction preventing further sales of Puff Bar's products "unless and until Puff Bar obtains Premarket Approval" or "is approved as a Modified Risk Tobacco Product," Am. Compl., ¶ 165(d), Plaintiffs are also deemed to have conceded that point. *Leisure Pass N. Am., LLC v. Leisure Pass Grp., Ltd.*, Civ. No. 2:12-cv-03375 (WJM), 2013 U.S. Dist. LEXIS 120593, at *10 (D.N.J. Aug. 23, 2013) ("Plaintiff has waived its opposition to this argument by failing to respond to it."); *Ferrante v. Amgen, Inc.*, Civ. No. 13-07344 (SRC), 2014 U.S. Dist. LEXIS 34975, at *18 (D.N.J. Mar. 18, 2014) (same as to a motion to dismiss).

into this exception, however, Plaintiffs' Amended Complaint provides no specific allegations regarding the nature or content of the Puff Bar advertising that minor Plaintiff J.S. allegedly saw, when and where he saw it, whether and how he relied on it, and the effect that it had on him, including whether it induced him to, for example, provide a false identification to illegally purchase Puff Bar products from New Jersey retailers. *See* Am. Compl., ¶ 10. Instead, the Amended Complaint merely states: "Plaintiff, J.S., has seen Puff Bar advertisements." *Id*., ¶ 9. This unadorned factual allegation, without more, is insufficient to state a claim of false advertising or to wedge Plaintiffs' claims into the narrow false advertising exception to preemption provided by 21 U.S.C. § 387p(a)(2)(B).[6]

II. PLAINTIFFS FAIL TO STATE A PLAUSIBLE CLAIM UNDER THE PLA.

Plaintiffs contend that their PLA claims are sufficiently pled and should not be dismissed because "Plaintiffs' claims in the instant case are [akin to] those pending against JUUL Labs, Inc." Opp. at 16. But Plaintiffs cite almost exclusively to authority from foreign jurisdictions that do not apply the PLA. And the only PLA case to which Plaintiff cites is not analogous. For those reasons alone, the authorities cited by Plaintiffs are inapposite and should be disregarded.

[6] Indeed, Plaintiff's claims regarding supposed inaccuracies in Puff Bar's comparison on its website of the nicotine content of its products with the nicotine content of combustible cigarettes, Am. Compl., ¶¶ 114-116, are difficult to square with Plaintiffs' claims that Puff Bar was designed to be attractive to youth and other individuals uninitiated to smoking combustible cigarettes and to Plaintiffs' allegations of harm to Plaintiff J.S. in the Amended Complaint. By way of example, absent any factual allegation that Plaintiff J.S. was a regular user of combustible cigarettes, Plaintiffs lack any basis to even begin to allege that such inaccuracies in Puff Bar's representations regarding the nicotine content of its products compared with the nicotine content of a pack of combustible cigarettes would have reasonably induced J.S. to try the product when he otherwise would not have had he known the actual nicotine content. Further, if J.S. was already a regular smoker of combustible cigarettes, Plaintiffs' claims that Puff Bar's products led him down the road to nicotine dependency and addiction would entirely lack any factual support. *See* Am. Compl., ¶ 11 ("Plaintiff, J.S. did not know how much nicotine Puff Bar contained . . . when he began using it. . . . He now suffers from nicotine addiction and other physical and personal injuries.").

In particular, Plaintiffs' heavy reliance on the JUUL case to support their state law claims is perplexing. That case is from the Northern District of California, not the District of New Jersey, and it interprets California product liability law, not the PLA. *See Colgate I*, 345 F. Supp. 3d at 1192 ("Pursuant to California law, a design defect may be established . . . ."); *id.* at 1193-94 (citing to California law to address manufacturing defect claim). Moreover, the decision does not address whether the plaintiffs in that case adequately pled a failure to warn claim, but only whether such a claim was preempted. *See generally id.* at 1191-96. Finally, the case involves an entirely different product than the one at issue here. As such, *Colgate* certainly does not support Plaintiffs' argument that their inadequately pled PLA claims survive dismissal.

Ultimately, Plaintiffs' Amended Complaint fails to meet the requirements of the PLA to state a plausible claim. Accordingly, it must be dismissed.

A. Plaintiffs Have Not Pleaded that the Puff Bar Products Failed to Contain Adequate Warnings.

Plaintiffs mischaracterize, and otherwise ignore, the basis of Puff Bar's motion to dismiss: that Plaintiffs' failure to warn claim under the PLA must be dismissed because Plaintiffs did not plead facts sufficient to overcome (or even address) the PLA's rebuttable presumption that Puff Bar's FDA-mandated and approved warning label is adequate. N.J. Stat. Ann. § 2A:58C-4; *see generally* Puff Bar Br. [Dkt. No. 37-1] at 22-23. As a result, Plaintiffs' failure to warn claim must be dismissed.

As explained in Puff Bar's opening memorandum, and undisputed by Plaintiffs, the Puff Bar product contains a warning that is both "approved" *and* "prescribed" by the FDA under the FDCA. *See* Def's. Memo. at 4-5 (citing Am. Compl. at 17); *id.* at 5-8 (discussing FDA); *id.* at 13-14 (discussing FDA labeling requirements for ENDS products); *see also* I.B., *supra*. The PLA explicitly provides that when an aspect of the product is unavoidably unsafe and the FDA mandates

or approves a warning that relates to that aspect of the product, such a warning gives rise to a rebuttable presumption that the warning is adequate. Further, unless that presumption is rebutted, the product containing the warning is immune from liability under the PLA on a failure to warn theory. *See* N.J. Stat. Ann. §§ 2A:58C-3(a)(3), 2A:58C-4; *see also Seavey v. Globus Med., Inc.*, No. 11-2240 (RBK/JS), 2014 U.S. Dist. LEXIS 65985, at *31 (D.N.J. Mar. 11, 2014) (holding no liability under PLA for failure to warn where plaintiff failed to rebut presumption in § 2A:58C-4).

The New Jersey Supreme Court has made clear that "[t]o overcome this presumption [in § 2A:58C-4], a plaintiff asserting a failure to warn claim based on an inadequate label or instructions has *stricter* pleading requirements." *Cornett v. Johnson & Johnson*, 211 N.J. 362, 388 (2012) (emphasis added). To plead a plausible failure to warn claim in the face of an FDA-approved label, "[a] plaintiff must plead specific facts alleging 'deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects,' or 'manipulation of the post-market regulatory process.'" *Id.* (citations & other internal quotation marks omitted); *see also Chester v. Bos. Sci. Corp.*, No. 16-02421 (FLW), 2017 U.S. Dist. LEXIS 26676, at *32 (D.N.J. Feb. 27, 2017) (same, citing *Cornett*).

Here, Plaintiffs do not attempt to argue in their opposition why, under controlling New Jersey law, their failure to warn claim should not be dismissed on the pleadings in light of the PLA's presumption.[7] Instead, relying almost entirely on California cases applying California law, Plaintiffs focus on whether nicotine is "unavoidably unsafe."[8] But, as it relates to the Puff Bar

[7] Plaintiffs do not even address the presumption in their opposition, and thus have waived any argument that it does not apply. *Leisure Pass N. Am., LLC*, U.S. Dist. LEXIS 120593, at *10; *Ferrante*, 2014 U.S. Dist. LEXIS 34975, at *18.

[8] Not only do none of these California cases involve the PLA, but there is nothing in those cases analogous to the PLA's rebuttable presumption. Instead, these cases address whether a danger can be considered open and obvious under California law, thereby obviating the need for a warning.

products, that issue is resolved – products containing nicotine are known to the be unavoidably unsafe. That is the very reason why FDA mandates a warning on Puff Bar's packaging that says: "**WARNING: This product contains nicotine. Nicotine is an addictive chemical."**

The only failure to warn decision under the PLA that Plaintiffs cite is *Fellner v. Tri-Union Seafoods, L.L.C.*, No. 06-CV-0688 (DMC), 2010 U.S. Dist. LEXIS 36195, at *1 (D.N.J. Apr. 13, 2010). As a preliminary matter, *Fellner* is of questionable value, as it pre-dates *Cornett*. Setting that aside, *Fellner* has no application here, as it did not involve an FDA-mandated product warning or the PLA presumption; rather, the plaintiff there argued that the product required a warning and the defendant argued that no warning was required under FDA regulations. *Id.* at **17-24. In contrast, here, there is no dispute that the FDA required a specifically worded warning about nicotine and its addictiveness, mandated a specific appearance in a prominent location on product packaging, and that Puff Bar met FDA requirements for this warning. Plaintiffs' failure to warn claim is based on the inadequacy of this warning. But, as explained above, Plaintiffs' claim fails under *Cornett* because Plaintiffs have not rebutted the presumption that this FDA-approved warning is adequate.[9]

Because Plaintiffs fail to allege facts that would justify overcoming the presumption in favor of the adequacy of the FDA-mandated warning, their failure to warn claim must be dismissed. *See Greisberg v. Bos. Sci. Corp.*, Civ. No. 19-12646, 2020 U.S. Dist. LEXIS 137257,

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As California law differs from the PLA in that California law does not contain the same presumption, Plaintiffs' California cases are inapplicable.

[9] Other than in bald, conclusory fashion, nowhere in Plaintiffs' amended complaint does it allege that Puff Bar marketed its product as a "safe" alternative to traditional cigarettes, as Plaintiffs now claim. *See* Opp., 17-18; *see also* Am. Compl., ¶ 38 ("Defendants market this highly addictive device as healthy, safe, cool and available in kid-friendly flavors."). Once again, Plaintiffs' "naked assertion[s] devoid of further factual enhancement" need not be granted any deference by the Court. *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

at *9 (D.N.J. Aug. 3, 2020) ("Because Plaintiff again fails to plead specific facts [as required by *Cornett*,] Plaintiff fails to overcome the NJPLA's presumption. Accordingly, Plaintiff's failure to warn claim is not adequately alleged, and therefore, the claim is dismissed.").

B. Plaintiffs Have Not Pleaded that the Puff Bar Products were Designed in a Defective Manner.

To plead a plausible claim for design defect, Plaintiffs must allege that the addictiveness of nicotine found in Puff Bar's products was not disclosed to consumers. No such allegations are found here (nor could they be); as a result, Plaintiffs have not pleaded that the Puff Bar product was designed in a defective manner.

As regards the three-part test established by N.J. Stat. Ann. § 2A:58C-3(a)(2), to the extent that Plaintiffs now claim that their defective design claim is not based on the presence of nicotine in Puff Bar's products as such, but rather on the amount, or "potency" of the nicotine in Puff Bar's products versus the amount of nicotine found in other electronic cigarettes or combustible cigarettes, the labeling of Puff Bar's products clearly states both that the product contains a salt nicotine formulation and the exact nicotine content of the product's e-liquid through the words "5% SALT NIC" or "Salt Nicotine: 5%." *See* footnote 1, *supra*, and Am. Compl., ¶ 69. Just as Plaintiffs studiously avoid acknowledging the prominent nicotine addictiveness warning in their Amended Complaint and Opposition, so they also pointedly avoid the fact that the salt-nicotine formulation and specific amount of nicotine are identified for the consumer on the product labeling. Considering the products' addictiveness warning and specific description of a five percent salt nicotine formulation, Plaintiffs cannot plausibly plead that ordinary consumers did not know or recognize that the products contained five percent salt nicotine, which was an inherent characteristic of the product, and that such presented an inherent risk of the harm of nicotine addiction.

Moreover, to the extent that Plaintiffs claim that consumers should have been more specifically warned of the risks inherent in a nicotine salt formulation, that claims runs headlong into Section 916's preemption language regarding labeling. *See Colgate I*, 345 F. Supp. 3d at 1188-89 ("Plaintiffs' labelling claims are preempted to the extent that they are related to JUUL's failure to warn consumers that pharmacokinetics of their formulation, even at a similar percentage of nicotine, is more potent than it would be in a traditional cigarette due to its chemical makeup."). As such, Plaintiffs fail to plead an actionable design defect claim. *Mercer Mut. Ins. Co. v. Proudman*, 396 N.J. Super. 309, 313 (App. Div. 2007) ("[U]nder the PLA, [i]f the harm caused by a product would be recognized by the ordinary person who uses or consumes the product and if the harm stems from an inherent characteristic of the product, then the harm is not actionable") (internal quotation marks omitted).

Similarly, to the extent that Plaintiffs' design defect claim is premised on alleged statements regarding the amount of nicotine in Puff Bar's products versus a pack of combustible cigarettes, as noted above, the Amended Complaint lacks sufficient non-conclusory factual allegations to suggest that Plaintiff J.S.—himself a minor who purchased the Puff Bar products illegally and thus could never be included in the categories of the "class of persons for whom the product is intended" or "ordinary consumer or user" of the product—ever observed any Puff Bar advertisement claiming that a single Puff Bar product contains an amount of nicotine equal to a pack of cigarettes. Nor does the Amended Complaint allege that Plaintiff J.S. perceived the Puff Bar product to be a healthier alternative to cigarettes or that he anticipated that the Puff Bar products would deliver nicotine at the same or a lower level than found in other electronic cigarettes or combustible cigarettes. Without these allegations, the Amended Complaint fails to state a claim upon which relief can be granted and must be dismissed.

Moreover, "at the pleading stage . . . a plaintiff must plead either that the product's risk [of harm] outweighs its [utility], or that an alternate design exists, in order to state a claim for a design defect under the NJPLA." *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 824 (D.N.J. 2019) (internal quotation marks omitted). But Plaintiffs fail to argue that the Amended Complaint contains any non-conclusory allegation "of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm without substantially impairing the reasonably anticipated or intended function of the product." *See id.* at 823-24 (citing *Cavanaugh v. Skil Corp.*, 164 N.J. 1, 5, 751 A.2d 518 (2000)). Plaintiffs do not argue this because they cannot: there is only one conclusory allegation in the entire Amended Complaint addressing harm-versus-utility: "The risks inherent in the design of Puff Bar products significantly outweigh any benefits of such design." Am. Compl., ¶ 137. This allegation is nothing more than a bare bones recitation of the pleading requirement and is, therefore, insufficient under *Iqbal*, 556 U.S. at 678. Plaintiffs' PLA failure to warn claim must be dismissed.[10]

CONCLUSION

For the foregoing reasons, Puff Bar respectfully requests that the Plaintiffs' Second Amended Complaint be dismissed in its entirety, with prejudice.

[10] Plaintiffs appear to recognize and concede that their "Second Cause of Action" for a preliminary and permanent injunction is merely part of their ultimate request for relief based on their first cause of action, and one that must rise or fall with the success of that claim. Opp. at 20. Because Plaintiffs have not plausibly alleged any claim under the PLA, and because Plaintiffs advance no other claim, Plaintiffs' Second Cause of Action for preliminary and permanent relief must also be dismissed.

Dated: November 30, 2020

Respectfully Submitted,

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Attorneys for Defendant Puff Bar

CERTIFICATE OF SERVICE

I certify that on this date I caused the Reply Memorandum in Support of Motion to Dismiss Plaintiff's Second Amended Complaint to be filed with the Clerk of Court for the United States District Court for the District of New Jersey by using the CM/ECF system and understand that electronic notice of the filing will automatically be sent all counsel of record.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

s/ Brian Keahi Steinwascher
Brian Keahi Steinwascher

Dated: November 30, 2020